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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,814	07/07/2004	Lars Lidgren	CU-3809 RJS	7178

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LADAS & PARRY LLP
224 SOUTH MICHIGAN AVENUE
SUITE 1600
CHICAGO, IL 60604

EXAMINER	
CATTUNGAL, SANJAY	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
11/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,814	LIDGREN ET AL.	
	Examiner	Art Unit	
	SANJAY CATTUNGAL	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-29 have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that the claims recite heating an object using ultrasound. Examiner would like to point out that the claims do not positively recite heating the tissue. The preamble teaches heating but it's not clearly understood if that heating is the source of treatment. Applicant is advised to clearly recite it in the body of the claims, how therapy is done using heat.

Information Disclosure Statement

2. The information disclosure statement filed 10/12/09 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. All foreign documents require a translation of the abstract to be considered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 1-12, 18, and 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U. S. Patent No. 5,720,287 to Chapelon et al. in view of U. S. Patent No. 5,471,988 to Fujio et al.**

5. Regarding **Claim 1 and 20-29,** Chapelon teaches a device for mini-invasive ultrasound treatment of an object, wherein at least one therapeutic ultrasound transducer is arranged for treatment of the object by generating an ultrasonic field; wherein the therapeutic ultrasound transducer comprises an elongated probe defining a longitudinal direction and being adapted to be introduced into the body towards the object to be treated and which probe comprises a front portion adapted to be located at, against or in the object (Abstract and Fig. 5 element 46); and wherein said probe comprises at least one transmitter element for generating said ultrasonic field and for transmitting the ultrasonic field through the front portion, wherein said transmitter element is arranged in a rear portion behind the front portion of the probe seen in the longitudinal direction (Fig. 5 elements 45 and 46).

6. Chapelon does not expressly teach heat therapy and wherein said front portion is configured to be thermally insulating, whereby the transmitter element does not heat or substantially not heat the front portion during operation.

7. Fujio teaches heat therapy (Col. 14 lines 28-35 and Claim 66) and wherein said front portion is configured to be thermally insulating, whereby the transmitter element

does not heat or substantially not heat the front portion during operation (Col. 45 lines 9-17).

8. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Chapelon with a setup to use heat therapy to treat tissue as taught by Fujio, since such a setup is well known in the art for treatment of tumors, HIFU treatment are very efficient in treating tumors, and moreover Chapelon teaches therapy using ultrasound, and Figure 14 of Chapelon suggests HIFU therapy, but is not expressly mentioned in the specifications. Moreover different ultrasound treatments are known to be performed using ultrasonic probes as such its obvious to combine them.

9. Regarding **Claims 2 and 5,** Chapelon teaches the use of a focusing device for focusing the ultrasound generated by the transmitter element. (Fig. 4 element 46)

10. Regarding **Claims 3 and 4,** Chapelon teaches focusing ultrasound waves in the tissue and hence it would be inherent that the focus range falls within 0.5 - 20 centimeters. (Fig. 5)

11. Regarding **Claim 6**, Chapelon teaches a lens to focus ultrasound waves (Col. 5 lines 40-42).

12. Regarding **Claims 7, and 9-11**, Fujio teaches X-ray and CT imaging for determining position of the target region (Claims 17).

13. Regarding **Claim 8,** Fujio teaches the use of marker (Claim 8).

14. Regarding **Claim 12,** Fujio teaches the use of an Xray camera or an MRI scanner to take images of the target region (claims 17 and 18).

15. Regarding **Claims 18, and 25-29**, Fujio device is capable of performing the functions in any part of the body as the system is not limited by the area of the body. Since the structure of the device remains unchanged it meets the functional limitations of these claims.

16. **Claims 13-17 and 19, are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapelon and Fujio in view of U. S. Publication No. 2005/0020918 to Wilk et al.**

17. Regarding **claims 13, 14, and 17,** Chapelon and Fujio teach all of the above claimed limitations but do not expressly teach the use of a CT Scan system for optical navigation.

18. Wilk teaches the use of a CT scan system for optical navigation. (Abstract)

19. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Chapelon and Fujio with an CT navigation device as taught by Wilk since such a setup would result in a location system which would precisely locate the tissue/target region to be treated/ablated as the precision and quality of images in CT is much more greater than that of x-ray.

20. Regarding Claim 16, use of metallic tantalum balls are well known within the X-ray arts and it would have been obvious to use them to mark or reference.

21. Regarding **Claims 15 and 19**, Fujio device is capable of performing the functions in any part of the body as the system is not limited by the area of the body. Since the

structure of the device remains unchanged it meets the functional limitations of these claims.

22. Regarding **Claim 16,** Fujio teaches the use of markers, and tantalum balls are a kind of markers, as such are obvious variants (claim 8).

23. Claims **8 and 16,** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapelon and Fujio in view of U. S. Publication No. 2005/0020918 to Wilk et al. further in view of U. S. Patent No. 6,370,418 to Bernoski.

24. Regarding Claims 8 and 16, Chapelon, Fujio, and Wilk teaches all of the above claimed limitations but do not expressly teach the use of tantalum balls as markers.

25. Bernoski teaches the use of tantalum balls as markers (Col. 4 lines 10-14).

26. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Chapelon, Fujio and Wilk with tantalum balls as markers as taught by Bernoski, since the use of markers would help locate the target region. Moreover use of tantalum balls as markers are known in the art.

Conclusion

27. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 10/12/09 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SANJAY CATTUNGAL whose telephone number is (571)272-1306. The examiner can normally be reached on Monday-Friday 9-5.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SANJAY CATTUNGAL/
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768